

REMARKS

Claims 55-59 and 64-73 were pending in the instant application. Of these, claims 55-59, 72, and 73 were withdrawn from consideration as allegedly being drawn to non-elected subject matter. By this Amendment, Applicant has canceled claims 55-59, 64-67, 69, 72, and 73 without prejudice to the right to present the subject matter of these claims in a future continuation or divisional application. Applicant has amended claims 68, 70, and 71 to address the Examiner's concerns as set forth in the February 23, 2004 Office Action. Applicant has added new claims 74 and 75. Support for the claim amendments and new claims can be found throughout the specification and claims as originally filed. Neither the amendments to the claims nor the newly added claims introduce any new matter. Upon entry of the present Amendment, claims 68, 70-71, and 74-75 will be pending and under examination.

The February 23, 2004 Office Action

Rejections Under 35 U.S.C. §112, first paragraph

The Examiner rejected claims 64-71 under 35 U.S.C. §112, first paragraph, as allegedly lacking enablement. In the rejection, the Examiner reiterated the previous position that the specification fails to teach one of skill in the art how to use the invention as broadly as claimed. In the Examiner's opinion, the specific mutations described in the specification are not representative of all non wild-type alleles. The Examiner's rationale as set forth in detail on pages 4-9 of the Office Action essentially repeats assertions made in prior Actions. The Examiner specifically has asserted that the specification fails to describe which non wild-type alleles are associated with ADHD and which are not, and has thus concluded that the mere presence of any single non wild-type allele within one of the recited genes of an individual is not sufficient to indicate an increased ADHD risk. The Examiner's position essentially remains that, based on the Examiner's interpretation of the data both in the specification and in the art, the claims are not enabled for a broad range of

polymorphisms, nor for a broad population base. Moreover, according to the Examiner, the specification fails to provide evidence that the particular subset of 22 analyzed genes supports any association with ADHD. In effect, the Examiner continues to argue that one could not reliably predict ADHD risk based on detection of one of the five genes recited in the claims.

In response, Applicant first notes that it appears that the Examiner still is not reading the data accurately, despite Applicant's previous explanations of these data, and Examiner's acknowledgment and apparent acceptance of the explanations. Applicant therefore respectfully again points out that the data, particularly as shown in Figures 3 and 4, indicate that the particular recited polymorphisms (i.e., of the norepinephrine and other neurotransmitter genes) are significant in their contribution to ADHD as determined by the disclosed methods.

Nevertheless, without conceding the correctness of the Examiner's position, but to expedite allowance of the subject application, Applicant has amended claim 68 to recite a method for determining whether a subject is at risk for Attention Deficit Hyperactivity Disorder (ADHD), comprising: determining for each of genes TPH, PNMT, ADOA2A, NOS3, and NAT1, whether the subject comprises a wild-type or non-wild type allele of said gene, wherein the presence of at least two non-wild type alleles selected from the group consisting of *TPH* SNP A 779C, *PNMT* SNP G-148A, *ADOA2A* SNP C108T *Rsa*I, and *NAT1* T1088A indicates that the subject is at risk for ADHD. the claims to recite methods. Applicant believes that the amendments to the claims overcome the Examiner's concerns and that the claims, as amended, are fully enabled by the specification. Accordingly, Applicant respectfully requests that the Examiner reconsider and withdraw the rejection under 35 U.S.C. § 112, first paragraph.

Rejections Under 35 U.S.C. §112, second paragraph

The Examiner rejected claims 64-71 under 35 U.S.C. §112, second paragraph, as being indefinite. Specifically, the Examiner indicated that there are two possible interpretations of claims 64-67 and has chosen to interpret these claims to not require the performance of the steps of claim

55, from which they depend. However, the Examiner has indicated that if the desire is to have the claims construed as requiring these steps, claim 64 should be rewritten to affirmatively recite them.

In response, without conceding the correctness of the Examiner's position, but to expedite allowance of the subject application, Applicant has canceled claims 64-67 without prejudice.

With respect to claims 68-71, the Examiner indicated that claim 69's recitation of "said at least one non-wild type allele . . ." lacks antecedent basis.

In response, Applicant points out that the claims as amended do not include the phrase referred to by the Examiner. In the light of the above amendments and claim cancellations, Applicant believes that the rejection under 35 U.S.C. §112, second paragraph, is fully overcome. Accordingly, its withdrawal is respectfully requested.

Rejections Under 35 U.S.C. § 102

Claims 64-67 were rejected under 35 U.S.C. §102(e) as allegedly being anticipated by U.S. Patent No. 6,132,724 (Blum), already of record. The Examiner asserted that the Blum patent teaches a method for determining the additive and subtractive effect of multiple genes using the MAA technique, and in particular, studying the additive effect of three adrenergic genes (ADRA1A, ADRA2C, and DBH) on ADHD.

The Examiner set forth additional rejections based on pieces of art already of record, all of which are based on Applicants' own publications. Specifically, claim 64 was rejected under 35 U.S.C. §102(b) as being anticipated by Comings, et al., Am. J. of Med. Gen., Vol. 67, pp.264-288, (1996). The Examiner asserted that this reference teaches analyzing individuals for risk of ADHD using polymorphisms of three different dopaminergic genes. Claims 64-67 were rejected under 35 U.S.C. §102(b) as being anticipated by Comings, et al., Clin. Genet., Vol. 55, pp. 160-172, (March 1999). The Examiner indicated that this reference teaches the additive effect of three adrenergic genes on ADHD.

Finally, the Examiner rejected claims 64-67 under 35 U.S.C. §102(b) as being anticipated by Comings, et al., Clin. Genet. Vol. 57, pp. 178-196 (March 2000). Applicant notes, however, that

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this reference is not available as prior art under 35 U.S.C. §102(b), as it was not published more than one year prior to the effective filing date of the current application.

In response to the above rejections, without conceding the correctness of the Examiner's position, but to expedite allowance of the subject application, Applicant has canceled claims 64-67 without prejudice, thereby rendering the rejection of these claims moot. Accordingly, Applicant respectfully requests that the Examiner reconsider and withdraw the rejections under 35 U.S.C. §102.

In view of the amendments and remarks set forth herein, Applicant believes that the present application is in condition for allowance. Reconsideration of the application and early notice of allowance are requested. The Examiner is invited to telephone the undersigned if it is deemed to expedite allowance.

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Respectfully submitted,

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